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The role of simulator training for skills acquisition in coronary angiography

by

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"Never assume the obvious is true"
William Safire

To my wonderful family
Ulrika, Viggo and Maja

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Abstract

Introduction

Coronary angiography (CA) is one of our most common invasive techniques in medicine today and is used to investigate coronary anatomy and pathology. The method is crucial and lifesaving in diagnosing acute coronary syndromes and so far not interchangeable to any other modality. The skills of performing a CA are compulsory for the general cardiologist according to present international guidelines but the methods for achieving these skills are not well defined. CA is a relatively safe procedure but complications occur, particularly during training. Simulators are proposed to be safe alternatives to achieve necessary skills but the methods for their use are not described. The aim of this thesis was to demonstrate that simulator training improve CA skills in real life. To be able to recommend simulators for skills acquisition, transferability from virtual reality to real life catheterization lab must be demonstrated, i.e. transfer validity.

Methods and results

Study I: The aim was to explore factors related to proficiency in CA and to construct learning curves to describe the improvement in CA skills over time. Swedish Coronary Angiography and Angioplasty Registry (SCAAR) was used to track experts and novel operators in CA and to compare their performances. Fluoroscopy time turned out to be the only solid marker for proficiency demonstrating a learning curve in the beginners group who reached expert level after 150 CAs. Complications were more frequent during training and were associated to fluoroscopy time.

Study II: The concept of simulator constructs validity, i.e. to demonstrate that the simulator can measure the differences it is supposed to measure was explored in study II. Twenty-four participants with three different levels of proficiency in CA performed five consecutive virtual reality CAs each in the simulator. Three different levels of skills in the simulator were demonstrated that corresponded to their proficiency level. Beginners had a fourfold increased risk of errors compared to the experts assessed by evaluating video recordings of their performances.

Study III: It was investigated if a structured simulator-based two day course in CA had any impact on the learning curve in CA. Twelve course participants continued to training in invasive cardiology and were tracked in SCAAR. Compared to a matched beginners group without simulator experience in SCAAR the virtual reality trained group demonstrated a less consistent improvement in fluoroscopy time previously discussed to be associated to proficiency. The complication rate was higher in the simulator trained group. Course transfer validity from virtual reality to real life was therefore rejected.

Study IV: In this randomized study it was explored if proficiency based training in CA could transfer skills achieved in virtual reality to real world. Sixteen senior cardiology residents were randomized to preparatory simulator training or control. The simulator group practiced in mean 10 hours in a CA simulator. Both groups performed thereafter two consecutive CAs on patients. The simulator trained residents outperformed the conventional trained residents in quality and safety of the procedure and had shorter fluoroscopy time reflecting higher proficiency.

Conclusion

Simulator training improves the performance in CA during training. The strongest factor related to proficiency demonstrating a learning curve was fluoroscopy time. The Mentice VIST™ simulator can differentiate between CA skills in different proficiency levels. Particularly fluoroscopy time demonstrated to correspond well to real life conditions. A structured course in CA involving non-proficiency guided simulator practice in CA had no impact on the learning curve in CA but with an increased risk of complications. Proficiency based skills training in virtual reality CA was superior compared to conventional mentor-based training in real life CA both in quality and in safety thereby proving the concept of transfer validity.

Sammanfattning

Introduktion

Kranskärlsröntgen är en av våra vanligaste invasiva tekniker i dagens sjukvård och används för att utreda kranskärlsanatomi och patologi. Metoden är avgörande och livräddande vid diagnostik av akuta koronara syndrom och ännu så länge inte utbytbar mot någon annan modalitet. Färdigheten att kunna utföra en kranskärlsröntgen är obligatorisk för den allmänna kardiologen enligt våra nuvarande internationella riktlinjer men metoderna för hur man ska uppnå färdigheterna är inte väl beskrivna. Kranskärlsröntgen är en relativt säker undersökning men komplikationer inträffar, i synnerhet under upplärning. Simulatorer har föreslagits vara ett säkrare alternativ för att uppnå nödvändiga färdigheter men metoden för dess användning är inte beskriven. Avsikten med denna avhandling var att visa att simulatorträning förbättrar färdigheterna i kranskärlsröntgen i verkliga livet. För att kunna rekommendera simulatorer för att förvärva färdigheter måste man kunna visa en överförbarhet från den virtuella verkligheten till verkligt kranskärlsröntgen lab, alltså transfer validitet.

Metoder och resultat

Studie I: Målet var att undersöka faktorer relaterade till erfarenhetsnivåer i kranskärlsröntgen och konstruera inlärningskurvor för att beskriva förbättring av färdigheter över tid. Svenska registret för kranskärlsröntgen och kranskärlsplastik (SCAAR) användes för att spåra nybörjare och experter i kranskärlsröntgen och för att jämföra deras prestationsförmåga. Genomlysningstid visade sig vara den enda stabila markören för färdighet och visade sig som en inlärningskurva hos nybörjarna som nådde expertnivå efter 150 kranskärlsröntgen. Komplikationer var få men vanligare under upplärning och associerad med ökad genomlysningstid.

Studie II: Konceptet med konstruktions validitet, dvs. att visa att simulatorn kan mäta skillnaderna den är avsedd att mäta, kunde påvisas i studie II. Tjugofyra studiedeltagare med tre olika erfarenhetsnivåer inom kranskärlsröntgen utförde fem virtuella kranskärlsröntgenundersökningar var i simulatorn. Tre olika nivåer av praktiska färdigheter utvisade sig som korrelerade väl till deras erfarenhetsnivåer. Nybörjare hade en fyrfaldigt ökad risk för misstag jämfört med experter utvärderat genom en bedömning av videoinspelningar av deras utföranden.

Studie III: Det undersöktes om en strukturerad simulatorbaserad tvådagarskurs i kranskärlsröntgen hade någon inverkan på inlärningskurvan i kranskärlsröntgen. Tolv kursdeltagare vidareutbildade sig inom invasiv kardiologi och kunde spåras i SCAAR. Jämfört med en matchad nybörjargrupp utan simulatorerfarenhet i SCAAR visade den simulator tränade gruppen en mindre konsekvent förbättring i genomlysningstid vilket tidigare diskuterats vara förknippat med erfarenhet. Antalet komplikationer var högre i den simulatortränade gruppen. Överföringsvaliditet för kursen från virtuell verklighet till verkliga livet förkastades därmed.

Studie IV: I denna randomiserade studie undersöktes om erfarenhetsbaserad träning i kranskärlsröntgen kunde överföra färdigheter inhämtade i virtuell verklighet till verkliga livet. Sexton seniora ST-läkare i kardiologi randomiserades till förberedande simulatorträning eller kontroll. Simulator gruppen tränade i genomsnitt 10 timmar i en kranskärlsröntgensimulator. Båda grupperna utförde därefter två kranskärlsröntgen på patient. De virtuellt tränade ST-läkarna utklassade de konventionellt tränade ST-läkarna i kvalitet och säkerhet i undersökningen och hade kortare genomlysningstid avspeglande högre skicklighet.

Slutsats

Simulatorträning förbättrar utförandet i kranskärlsröntgen under upplärning. Den starkaste faktorn relaterat till erfarenhet och som visade sig som en inlärningskurva var genomlysningstid. Mentice VIST™ kan skilja på olika kranskärlsröntgenfärdigheter för olika erfarenhetsnivåer. I synnerhet genomlysningstid visade sig överensstämma väl med förhållandet i verkliga livet. En strukturerad kurs i kranskärlsröntgen med icke erfarenhetsguidad simulatorträning i kranskärlsröntgen hade ingen inverkan på inlärningskurvan i kranskärlsröntgen utan medförde en ökad risk för komplikationer. Erfarenhetsbaserad färdighetsträning i virtuell kranskärlsröntgen var överlägsen konventionell mentorbaserad träning i kranskärlsröntgen i verkliga livet både i kvalitet och i säkerhet, och därmed påvisades transfer validitet.

LIST OF ORIGINAL PAPERS

This thesis is based on the following studies, which will be referred to by their Roman numerals

I
Ulf Jensen, Bo Lagerquist, Jens Jensen, Per Tornvall
The use of fluoroscopy to construct learning curves for coronary angiography
Catheter Cardiovasc Interv 2012;80(4):564-9.

II
Ulf Jensen, Jens Jensen, Göran K. Olivecrona, Gunnar Ahlberg, Per Tornvall
Technical Skills Assessment in a Coronary Angiography Simulator for Construct Validation
Sim Healthcare 2013; in press

III
Ulf Jensen, Jens Jensen, Göran Olivecrona, Gunnar Ahlberg, Bo Lagerquist, Per Tornvall
The role of a simulator-based course in coronary angiography on performance in real life cath lab. A case-control study.
Submitted manuscript

IV
Ulf Jensen, Jens Jensen, Gunnar Ahlberg, Per Tornvall
Proficiency-based simulator training in coronary angiography outperforms conventional mentor-based training - A randomised transfer study.
Submitted manuscript

List of Abbreviations

ACC	American College of Cardiology
CA	Coronary Angiography
CABG	Coronary Artery Bypass Grafting
CIN	Contrast Induced Nephropathy
CRM	Cardiac Rhythm Management
CRT	Cardiac Resynchronization Therapy
EAPCI	European Association of Percutaneous Cardiovascular Interventions
EP	Electro Physiology
ESC	European Society of Cardiology
EVAR	Endo Vascular Aortic Aneurysm Repair
IQR	Inter Quartile Range
IRR	Inter Rate Reliability
LCA	Left Coronary Artery
MRT	Mental Rotation Test
OR	Operation Room
PCI	Percutaneous Coronary Intervention
RCA	Right Coronary Artery
SBME	Simulator Based Medical Education
SCAAR	Swedish Coronary Angiography and Angioplasty Registry
SD	Standard Deviation
SFA	Superficial Femoral Artery
TAVI	Transcatheter Aortic Valve Implantation
TEVAR	Thoracic Endovascular Aortic Aneurysm Repair
VIST™	Vascular Intervention Simulation Trainer
VR	Virtual Reality

Introduction

History of coronary angiography

The first cardiac catheterization was made 1929 by Dr.Werner Forssmann introducing a catheter from the cubital vein to the right side of the heart. Dr Forssmann acted double roles of physician and patient performing the procedure on himself (1). An intensified development in invasive cardiology was thereby initiated. Almost 30 years later the first selective coronary angiography was performed 1958 serendipitous by Dr. Mason Sones when performing catheterization on a 26 year old male patient. The catheter, supposed to inject contrast into the ascending aorta, accidently slipped into the right coronary ostium depositing a large dose of contrast into the artery creating a beautiful coronary radiographic imprint. The patient reacted with a transient heart arrest followed by bradycardia due to the contrast used but the situation was successfully managed by injection of atropine sulfate intravenously (2). This rather dramatic event was the start of a new era of invasive cardiology and was a major contribution to the diagnostic armamentarium in cardiovascular medicine. However, important innovations and discoveries were made prior to this regarding catheters and imaging techniques and the development after this event has been focusing on improvement of quality and safety of the material and equipment used (3-7). An important innovation was made by Dr. Sven Ivar Seldinger 1953 who described a percutaneous vascular access rather than a cut down and this technique has since then been the gold standard way of entering the blood vessel (8). Coronary angiography (CA) is now one of the most common invasive procedures in medicine exceeding 2 million procedures annually in the world and still the gold standard for imaging of the coronary vessels. However, after the rather dramatic start of this new era, diagnostics were associated with frequent complications in the initial decades though with an impressive improvement in safety of the procedure up to date (9-11). The procedure is still associated with complications but the general opinion is an aim for a zero tolerance for complications in CA.

Medical errors

Medical errors created by human factors causing iatrogenic illness are always negative to the patient and in a worst case scenario fatal. To the individual causing the error the result can be almost as dramatic resulting in juridical consequences with lawsuit or suspension from work. For the community the result will be a financial issue reaching enormous sums with estimations from the US to billions of dollars. Calculations from the US also report on as many as a 100 000 lives lost due to medical errors and similar estimations from Sweden reach 3000 lives (12,13). Based on these facts, the medical community started to think in terms of increased patient safety through safe training. Inspired by the traditions from the aviation industry with advanced simulators to enhance training to prevent accidents, development of medical dummies and simulators of increasing complexity started to grow. Initially simulators for surgical procedures were invented but soon a more diverse arsenal of advanced virtual reality training tools were developed, including simulators for complex cardiovascular procedures (14).

Diagnostic CA is a procedure associated with a 0.8-4.6% risk for morbidity and a 0-0.2 % risk of mortality (9,15-21). Errors related to CA are more common during training and most commonly associated to the access site (10). However, despite that bleedings from access sites usually are minor or moderate they have impact on morbidity and prognosis (22). Far more serious is complications related to internal bleeding or thrombo-embolic events resulting in cerebral bleeding/emboli or myocardial infarctions. Such complications are fortunately rare but catastrophic when they appear. Intra-procedural radiation doses given to patients have become an increasingly important question since studies report on an increased risk for cancer. Unfortunately this is a deficiently investigated issue regarding the risk for the catheterization lab staff (23,24). Contrast-induced nephropathy (CIN) is another issue affecting patients undergoing even simple diagnostic procedures resulting in morbidity and mortality for the patient and high costs for the community (25,26). Ways of reducing both radiation and CIN are necessary to improve the outcomes of the procedures. Safe training and skills acquisition is warranted and simulators are proposed to be one answer for training outside the catheterization laboratory or operation room (27,28). Guidelines for training of the general cardiologist recommend using simulators as a tool for skills acquisition but the methods for how to practice this training is missing. Furthermore patients are no longer interested in being training objects for future invasive doctors and have lower threshold for accepting complications and medical errors and are therefore enlightened about alternative training methods.

Theories on learning and competence development

Historically, learning skills, especially practical skills have followed the master apprentice principle by expert supervision and a trainee who stepwise take over parts of the procedure to finally perform the whole procedure without a supervisor thereby reaching proficiency. The philosophical and pedagogical methods for reaching proficiency or competency have been described in several different ways and models and also demonstrated the different phases the learner go through in the learning process. This section will present a short overview of different theories of learning processes and competency development.

The learning process can be described in four stages of competence, first presented by Noel Burch some 40 years ago: *Unconsciously incompetent* relates to the stage where the trainee is so incompetent that he/she is unaware of it. In this stage the trainee is not able to recognize their deficit. *Consciously incompetent* relates to the stage where the trainee finally can appreciate the difficulties of a task to be able to recognize their incompetence. *Consciously competent* relates to the stage when the trainee understands and knows how to do the procedure though dependent on concentration through the procedural steps. *Unconsciously competent* relates to the stage when the procedure is performed without reflecting over it, becoming a second nature. Automation has occurred. *Reflectively competent,* this fifth stage has been added by some users to describe the “conscious competence of unconscious competence”, a stage the unconsciously competent has to enter when teaching, thus must be able to reflect and move out of the “auto pilot” mode.

In 1967 Fitts and Posner presented a model of learning complex motor skills in three phases (29). The first phase represents the *cognitive* (or understanding) *stage* where the learner focus on cognitive problems associated with the task to be performed. This stage is associated with a high variability in the performance and a large number of errors, with few signs of actual learning and improvement. Neural pathways for specific movements are forming. This is the stage when the learner is figuring out the skill and what to do to get better. The time spent in the cognitive stage is usually brief. The second stage is called the *associative* (or practice) *stage.* The amount of training to complete this stage is highly individual and dependent of the task complexity. To improve the trainee has learned to associate different key skills to environmental circumstances and also improved to detect errors related to their own performance and correct them thereby improving consistency and variability of their performance. To summarize this stage, the learner is actually getting better. The *autonomous* (or automatic) *stage* is the final and third stage which is reached after an extended amount of practice. The skills performed in this stage is done almost without a conscious thought and regarded as the performer's second nature. The neural pathways are complete and no mental effort is needed to perform the skill.

Dreyfus and Dreyfus presented in 1988 a model a bit similar to Fitts and Posner's regarding motor skills but added the acquisition of cognitive skills (30). The original version consisted of five levels but an updated version added a sixth level. The characteristics and definitions of the different levels are: *Novice:* uses rigid adherence to rules and plans and has little ability to put the information into context. *Advance beginner:* has the ability, based on previous experience, to sort out relevant information and rules, is still limited in situational perception but uses analytic reasoning to solve problems. *Competent:* has the ability to see actions in terms of longer-term goals, still requiring analytic reasoning in more complex tasks, is conscious deliberate planning through the procedure. *Proficient:* uses holistic views to analyze situations and is able to identify the key elements in a situation, is able to identify deviations from the normal pattern. *Expert:* uses only analytic reasoning in new situations or when problems occur, not dependent on rules or guidelines, gets an intuitive grasp of a situation based on deep understanding, is prepared to expect the unexpected. *Master:* is able to see beyond the situation and uses unconscious practical wisdom to solve problems, is able to prevent situations before they appear.

Theories on learning motor skills

Performing surgical tasks are highly dependent on accurate motor skills. Motor skills can be classified in several ways and can help to better understand the complexity of the task (31,32). Motor skills may be classified in terms of three different groups of characteristics. First the precision of the movement – *fine* or *gross*, refers to the muscle groups used, where *a fine movement uses* small groups of muscle and *gross* uses larger muscle groups. Motor skills can also be characterized in the stability of the movement– *open* or *closed. Closed* skills are performed in a stable and predictable environment and skills performed in a changing unpredictable environment are said to be *open.* Finally, the skills can also be described in terms of when the skills begin and when it ends– *discrete, continuous* or *serial.* A *discrete* skill has a clearly defined starting and finishing point. If the start and finishing point is somewhat more unspecified it is said to be a *continuous* motor skill. Instead a *serial* motor skill is when a series of discrete motor skills is put together and must be performed in a specific order to be executed accurately. The motor skills required to perform a CA can be characterized as *fine, open* and *serial.*

Learning curves

Basically every procedure involving manual handling can be described in a performance curve and when learning appears a learning curve (33). A learning curve is the rate of learning over time. The actual learning curve has many features and can be characterized into four different types (Figure 1).

In the *linear curve* there is a direct correlation between skills improvement and the number or time practiced. In the *fast start curve* the beginner makes a fast progress initially which in turn

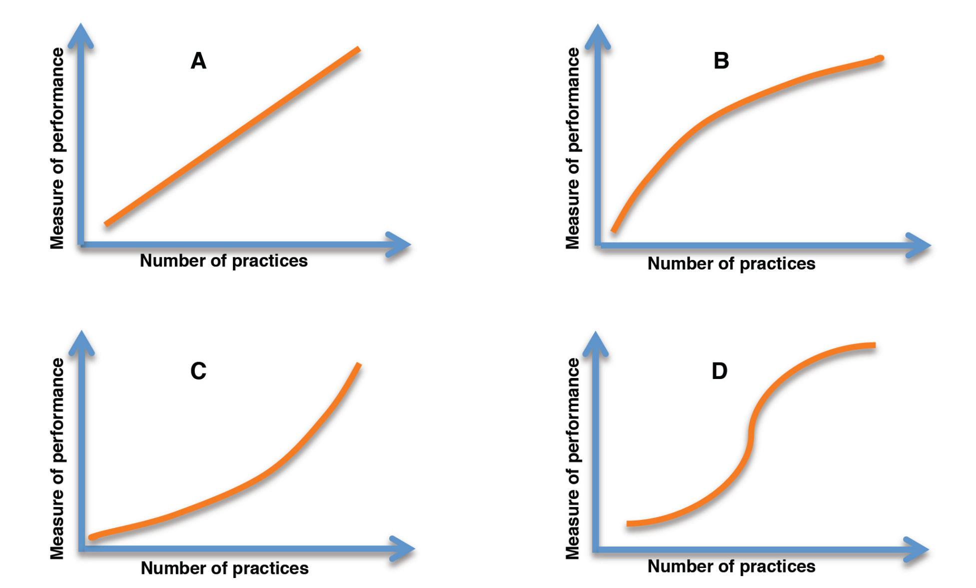


Figure 1. Characteristics of learning curves; A) the linear curve B) the fast start curve C) the slow start curve and D) the stop-start curve.

slows with on-going practice. The trainee quickly masters the basics but slows down when facing the more complex aspects of the skill. If the learner struggles to acquire the basic skill but when he has got the hang of it quickly progress he will represent the *slow start curve*. In the *stop-start curve* fast improvement will alternate with slow improvement, so called plateaus, and is probably the most common pattern of learning.

Teaching practical skills

Teaching practical skills is far different from teaching cognitive skills or theories. Skills performed by hand or interventions by humans using different tools and equipment require not only knowledge and understanding of the procedure to be performed but also physical dexterity.

For the trainer there are some difficulties and challenges about teaching practical skills, not only dependent on the personality of the pupil but also of the trainer. For the trainer it is important to take into consideration the fact that learners are different and have different preferences to learning styles. Behaviorists or experiential learners become frustrated listening to extended theory lectures and just want to go out and try. On the other hand the theorists need to understand every detail and the full context of the procedure before trying the practical aspect of the skill. Recognizing these differences in learning styles is an important factor for developing successful training programs. How skills are practiced will determine the progress of the skills acquisition and performance (34-37). Different practicing methods for practical skills have natural limitations and advantages and can be categorized as follows; *speed* and *accuracy, massed* and *distributed, whole, stepwise* and *progressive parts. Speed* refers to the rate of the procedure performed and *accuracy* the precision and exactness. The importance of speed and accuracy depends on the task performed. *Massed* practice refers to a continuous training period with only short breaks. *Distributed* practice refers to a training period where practice of the primary skill is not longer than the practice of other skills. Both methods are effective when practicing basic skills but distributed practice is considered more effective in improving performance since it allows time for feedback (38). A *distributed* practice with small blocks of practice with frequent brakes is preferable for beginners of a task. If the trainee should practice the *whole* procedure or have a *stepwise* approach depends of the learning stage of the trainee and of the complexity of the skill. A *stepwise* practice can be useful for novices (Fitts and Posner's cognitive stage) or when practicing a new skill. For the more experienced trainee (autonomous stage) this approach of part training can be useful to refine specific key skills. If the skill practiced is considered to be of a simpler nature *whole* practice is recommended. However, skills are not easily differentiated into simple or complex and therefore a mix of the two methods might be more appropriate. *Progressive part* practice refers to a type of practice where parts of a complex skill are practiced separately, slowly added together until the whole skill is practiced.

In analogy to progressive part practice, when reaching a more proficient state of skills, deliberate practice is said to be efficient in training key skills. This means that the skills most crucial for the performance are practiced over and over again until it becomes automated, a fact well known in sports and also demonstrated in simulator training (39). The more complex a task gets the more preparation is needed not only in theoretical knowledge and in skills practice but also in mental practice. Mental practice is said to be a cognitive way of visualization of a complex task. It is also a way of getting prepared for a complication or event, likely or unlikely to happen (40). This is the truth in skills said to be open, like almost every skill practiced in medicine due to its unpredictable nature. The *master* in Dreyfuss & Dreyfuss model (see above) has this ability in its nature and automatically incorporated in the preparations of the performance.

One widely used training method is "the four step model for teaching skills" which has been used in surgical training and particularly in advanced trauma life support (ATLS) courses and is well adjusted for teaching practical skills (41,42). This teaching model is divided into *real life demonstration* where the mentor demonstrates the entire procedure and skills needed without commenting, *mentor talk trough* demonstration when the trainer repeats the procedure, explaining each step and communicating with the trainee, *trainee talk through* guiding and instructing the mentor through the whole procedure and *trainee does* when the learner performs the procedure under close supervision. This teaching method might be useful in several situations and the first two steps can easily be prepared by video or e-learning thus saving time and cost and is easily rehearsed.

Validation and assessment theories

According to Dorland's medical dictionary the definition of validity is described as ”the extent to which a measurement, test, or study measures what it purports to measure" (43). When discussing validity one usually refers to five different types of validity: *Criterion validity* refers to the degree a new measurement correlates to a well established measurement procedure. *Construct validity* refers to the extent to what was supposed to be measured actually was measured. *Content validity* refers to the extent the test reflects the whole context of a measurement. *Face validity* refers to the degree the test object experience the reality of a test or examination. *Transfer validity* refers to the extent an acquired skill in a test can be transferred to a real life situation. When using simulators in training all validation modalities should be fulfilled to facilitate an optimal training environment, however, this is rarely the case.

In medical simulators the content can never reach true validity since the variables in a patient are so much more complex and cannot thus be expressed in virtual reality. Face validity struggles with the fact that the trainee knows that the training situation is not "real life" and therefore cannot experience the "real situation" to a full extent knowing that mistakes will not lead to "real life" complications. Some simulators have passed the transfer validity test meaning that the virtual training actually improves the post training performance in real life and this is probably the most important and perhaps even the only validity the simulator training needs to motivate their use and existence.

Assessing skills is usually referred to as formative or summative. Formative assessment is associated to the continuous practice or rehearsal of the skill and is usually performed during and after a training period. The purpose of this assessment is to promote an optimal training effect. Training without supervisors is therefore deficient of formative assessment however the assessment after a training period but before examination is formative. Summative assessment or examination is related to the gathered knowledge of the trainee and is usually benchmarked to certain performance criteria. Formative assessment usually creates an improved summative assessment hence correlated and necessary for a good training result. Basically two different assessment methods are used in medical simulator training studies, checklists or global rating scales adjusted to fit the specific procedure. The sensitivity in these two different evaluation methods depends on the object assessed. A well known and used instrument is the Objective Structured Assessment of Technical Skills (OSATS) representing both methods (44-46). According to the literature, checklists and global rating correlates differently to proficiency levels (47). Checklists are somewhat more objective and might therefore be easier to handle and evaluate. Also in a procedure like CA where errors can have catastrophic consequences, checklists or error scales might be more appropriate assessment tools than global rating. Global rating correlates stronger with experts and checklist correlates stronger to beginners or trainees and therefore different assessment tools should be used according to the proficiency level. The weakness in a global rating is that the evaluation procedure often is subjective demanding assessors with good inter-rater reliability.

Miller's pyramid "The Skills Hierarchy" presented in 1990 has been used for assessing clinical competence and learning outcomes (48) (Figure 2).

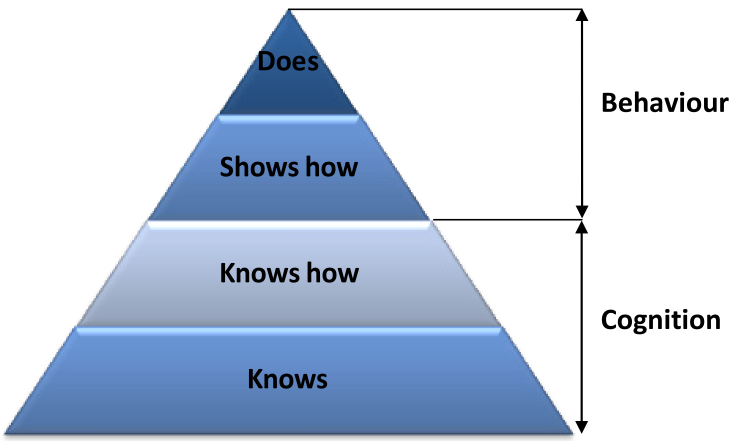


Figure 2. The Skills Hierarchy, by Miller.

In the base of the pyramid the trainee has an appropriate *know*ledge of the procedure to be performed. *Knows how* represents the stage to which the trainee has learnt to associate the cognitive knowledge to the performance skills. When the trainee has obtained the cognitive skills acquired and learnt to associate it to the skills to be performed it is time to *show how* where the learner demonstrates the procedure to be assessed. The highest level of performance is *does* which corresponds to the autonomous stage in Fitts and Posner's model. According to the theory by Miller, cognitive skills should be assessed with a written objective examination. According to the previous discussion the *show how* level should be assessed with checklist-type examinations and *does* by a global rating scale of examination in a clinical setting.

Donald Kirkpatrick presented in 1998 a four-level training evaluation model as an extension of Miller´s pyramid: r*eaction, learning, behavior* and *results. Reaction* represents a basic level relating to the trainees reaction and satisfaction to the training program and the evaluation should include attitudes to the program as a whole as well as specific components. *Learning* and *behavior* corresponds to Miller´s levels and are unlikely to occur unless the learner has a positive attitude to the training program. *Results* however is an extension of Millers *does* where the trainees´ learning is associated to the clinical outcome and improvement of the patient (49).

Medical simulators

One definition of a simulator is "*a device or exercise that enables a participant to reproduce or represent, under test conditions, phenomena that are likely to occur in actual performance"*(50). Simulators for practical skills training in medicine in general and surgery in particular have been present for the last four decades (51-53). The technology has improved tremendously over the years but the incorporation into training curricula has been disappointingly slow. Perhaps even more discouraging is that current simulators often are used without previous validation and transfer assessment in workshops and courses in different medical specialties, thus without a proven benefit. Cardiovascular intervention simulators saw the daylight more than a decade ago and still not much effort has been made trying to validate the training effect in a randomized transfer setting in these complex virtual reality training tools. A common feature of all simulators is their ability to provide proximate feedback about technical issues regarding the procedure being performed. Some simulators also have the ability to provide tactile or haptic feedback. Proximate feedback concerning technical skills is essential for the training effect but the role of haptic feedback is somewhat more uncertain and poorly investigated for obtaining new skills.
The basic goals of simulator training can be summarized into seven aspects:

- Improve skills through interval practice
- Improve consistency of performance
- Decrease errors
- Provide proximate and summative feedback
- Allow for assessment of progress
- Incorporate a standardized comprehensive curriculum
- Optimize patient safety by accelerating the learning curve prior to patient exposure

Current cardiovascular simulators on the market are:

Mentice VIST™; the first simulator on the market in this field holding a position as one of the most refined and advanced cardiovascular simulator. Mentice VIST™ contains application for CA, percutaneous coronary intervention (PCI), cardiac resynchronization therapy (CRT) lead placement, transseptal puncture, peripheral angiography, renal intervention, iliac/ superficial femoral artery (SFA) intervention, below-the-knee intervention, endovascular aortic repair, carotid intervention, neuro intervention and uterine artery embolization. This is also the most validated endovascular simulator regarding construct validity to date. Mentice VIST™ was the simulator used in our thesis (Figure 3).

Simbionix ANGIOMentor™; an advanced simulator containing applications for CA and PCI, transcatheter aortic valve implantation (TAVI), transseptal puncture, cardiac rhythm management (CRM), electro physiology (EP) basic skills, cerebral intervention, endovascular aortic aneurysm repair (EVAR), thoracic endovascular aortic aneurysm repair (TEVAR), carotid intervention, renal intervention, SFA/iliac interventions and below-the-knee interventions. This simulator has also incorporated ultrasound training.

CATHIS® simulator; is a somewhat less complex simulator, for the moment only containing applications for CA and PCI.

Simsuite®SIMANTHA®; holds applications for CA and PCI, balloon valvuloplasty, transseptal puncture, right heart catheterization, peripheral vascular interventions, neural interventions, renal interventions and carotid interventions.

Current evidence of transferability

Never assume the obvious is true! The use of simulators is today widespread in several training situations and the common opinion is that it must work and it is of benefit without any doubts (28,54-65). However, current evidence for transferability is missing for many simulator procedures. Several companies in the medical device industry with an ambition to educate physicians have one or several training centers equipped with advanced simulators. Offering courses with simulator training involved is popular but the effect of this training

Figure 3. Mentice VIST™ simulator used in the studies.

has almost never been evaluated. High costs for the industry as well as for the hospitals allocating doctors for workshops and courses is rarely questioned but an important issue if no benefit from this training is proven (66). Transferring the effects of achieved skills in simulators to real world and to reduce medical errors or complications are the main purposes of VR training. However, evidence of transferability from VR to real life is scarce and randomized transfer studies are warranted. Existing positive evidence for the ability to transfer acquired skills during simulator training to humans in randomized controlled trials are limited and can be summarized in the following Table 1. Each of these thirteen trials managed to show in a randomized setting that skills acquired during pretest simulator training resulted in an improved behavior in real life using seven different simulator procedures. Only two of these involved endovascular procedures, one in a cardiac procedure and none in a coronary procedure. The number of participants was limited in all studies and the outcomes can be summarized in either reduced procedure time or improved performance based on different global rating scores.

Table 1. Current randomized controlled transfer validation studies

Author	Ref	Year	Objective outcome	Subjects	Simulator	Procedure
De Ponti	(67)	2011	Reduced post-test training time	14	Mentice VIST	Cardiac transseptal puncture
Ahlberg	(68)	2007	Reduced operating time	13	LapSim	Laparoscopic surgery
Chaer	(69)	2006	Higher checklist and global rating score	20	Mentice VIST	Peripheral vascular intervention
Knoll	(70)	2005	Reduced procedure time	20	UroMentor	Ureterorenoscopy
Hochbereger	(71)	2005	Higher global rating score	23	compactEASIE	Endoscopy skills
Grantcharov	(72)	2004	Reduced operating time	16	MIST-VR	Laparoscopic surgery
Sedlack	(73)	2004	Increased patient comfort	38	Accutouch	Colonoscopy
Blum	(74)	2004	Higher global rating score	13	Accutouch	Broncoscopy
Di Guilio	(75)	2004	Higher global rating score	22	GI-Mentor	Upper endoscopy skills
Seymore	(76)	2002	Reduced procedure time	16	MIST-VR	Laparoscopic surgery
Hamilton	(77)	2002	Higher global rating score	19	MIST-VR	Laparoscopic surgery
Rowe	(78)	2002	Reduced procedure time	20	Accutouch	Broncoscopy
Ost	(79)	2001	Reduced procedure time	6	Accutouch	Broncoscopy

Building a curriculum

The core curriculum for cardiology was published a few years ago by the education committee of the European Society of Cardiology (ESC) stating the ideal pattern of the practical training for the general cardiologist (27,80). This curriculum was approved by national society members of the ESC and was based on a general opinion about the minimum requirement for the general cardiologist in theoretical knowledge and practical skills (81). However, a valid curriculum should not be based on a general opinion. Instead it should consist of a scientifically well-documented theoretical content and a scientifically validated training curriculum resulting in a safe and improved performance in real life procedure. The curriculum should also reflect on professionalism in behavior towards patients and colleagues.

To summarize and conclude the introduction, we should be able to build a valid curriculum in CA based on appropriate theories about achieving knowledge and practical motor skills and the type of training to best fit CA. We should also be able to pin-point the right assessment methods for cognitive and practical skills to secure that the trainee has reached the appropriate performance level and leveled out in learning curves before exposure to patients. This will be discussed in the general discussion and an attempt to a validated curriculum will also be presented.

Aims

The general aim of this thesis was to investigate if simulators can improve the learning of practical skills in CA.

The specific aims of the studies were:

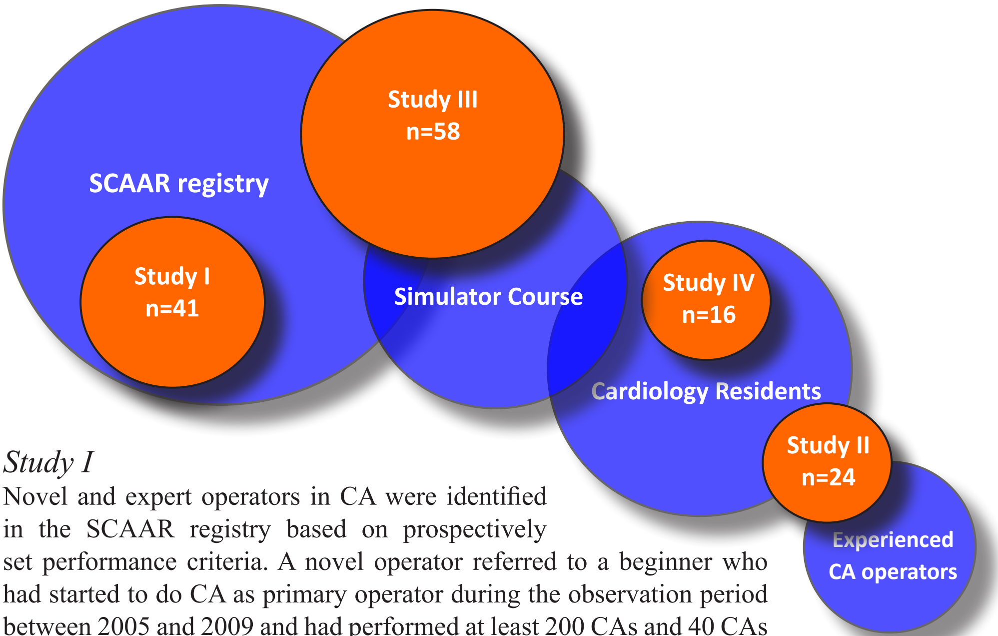
- To analyze the Swedish Coronary Angiography and Angioplasty registry (SCAAR) to create learning curves for beginners in coronary angiography and to define metrics related to proficiency.
- To investigate if a CA simulator can differentiate between different performance levels in metrics extracted from the simulator and the procedure to prove the concept of construct validity.
- To investigate if a dedicated simulator-based course in CA improves the learning curves for novel operators in Sweden tracked in the SCAAR registry to prove the concept of course validity.
- To investigate if cardiology residents randomized to proficiency-based simulator training in CA perform better than traditionally trained residents to prove the concept of transfer validity.

Material and Methods

Study subjects

In this thesis residents in cardiology in Sweden and groups of novel and experienced operators in coronary angiography from the SCAAR registry and from the Stockholm Metropolitan Area, respectively were studied (Figure 4).

Figure 4. Study subjects numbers



Study I

Novel and expert operators in CA were identified in the SCAAR registry based on prospectively set performance criteria. A novel operator referred to a beginner who had started to do CA as primary operator during the observation period between 2005 and 2009 and had performed at least 200 CAs and 40 CAs annually. An expert was an operator who had performed >1000 CAs during 10 years and a least 40 CAs annually during the observation period. According to these criteria we could identify 20 operators qualifying as beginners and 21 as experts.

Study II

Ten residents in cardiology without experience in performing CA, 4 senior residents with some experience in performing CA (range 73-163) and 10 expert CA performers with experience of > 3000 CAs each were recruited from five different hospitals in the Stockholm Metropolitan Area between 2006 and 2011.

Study III

Fifty-four residents in cardiology participated in the simulator-based CA course between 2006 and 2011 given at two different sites in Sweden. Twelve of the course participants progressed to become invasive cardiologists. These future interventionists were compared to a similar beginners group identified from the SCAAR registry who never attended the course.

The definition of a beginner was set to be an invasive cardiologist who started to perform CA between 2005 and 2012 and had performed at least 80 CAs and at least 40 CAs annually. A total of 58 novel operators were identified in Sweden during the observation period of seven years. Twenty percent attended the course during these years. Cases (n=12) and controls (n=46) were tracked in the SCAAR registry and proficiency metrics compared.

Study IV

Fifty-four cardiology residents from the Stockholm Metropolitan Area were invited by e-mail and direct contact with the hospitals during 2011 and 2012 to take part in this study. Thirteen of these residents had previous experience in CA simulator training and were thus excluded. Twenty-one residents did not respond or were not interested in participating. Twenty senior cardiology residents finally volunteered to participate. Four participants were not able to complete the study.

SCAAR registry

The SCAAR registry, which is a part of the SWEDEHEART registry, is a Swedish national database that registers all interventional coronary procedures since 1991. The register became web-based in 2001 and all procedures in the country are registered on-line with automatic data surveillance. The registry is sponsored by the Swedish Health Authorities and independent of industrial financing. All hospitals that perform CA (*n*=30) and interventions (*n*=29) register their procedures. The register holder of SCAAR is Uppsala Clinical Research Center, Sweden. SCAAR was used in study I and III to track and identify beginners and experts (paper I) and beginners (paper III) in CA. In study I, we aimed to find parameters that could define proficiency in CA and analyze these to be able to construct learning curves for CA. About 50 variables are used in SCAAR to describe the CA procedure. Potential proficiency data in CA from SCAAR were downloaded from UCR in Uppsala and recoded to be able to analyze the data in statistical programs. Parameter data to be used and compared were contrast volume, fluoroscopy time and complication rate. Potential proficiency parameters as total time and radiation dose could not be used because it is not registered in the first case and unrepresentative in the second case due to differences in x-ray systems in Sweden. In study III, we used the same parameters as in study I for proficiency analysis but we investigated instead all novel operators during a period of seven years and analyzed their learning curves and complications rates.

Simulator training and skills assessment

In paper II-IV, we used the Mentice VIST™ for skills practice in CA. In paper II, we aimed to explore the construct validity of the simulator in CA which not had been presented before. To be able to demonstrate construct validity, we had to show that the simulator could distinguish between different levels of performance. Three groups of performers with different expertise were recruited. All participants were simulator naive. During video filming they all performed five consecutive CAs in the simulator while recording skills parameters from the simulator as well as manually recording parameters as coronary intubation times. A total of 30 hours of video recordings were analyzed by two senior highly experienced CA operators blinded to the participant's proficiency and rated, with help of a checklist, with high inter-rater reliability. Based on the performance results from the expert group we could define the expert level for proficiency in CA in Mentice VIST™ to be used in the final transfer study.

In paper III, the Mentice VIST™ was used in a structured simulator-based course in CA. The course was announced and advertised in Sweden by ads in the Swedish Journal of Cardiology and by direct mail to all cardiology units in Sweden. The course was given 2-4 times every year between 2006-2011. The course size was limited to six participants at every occasion to guarantee high simulator exposure on the two available simulators. The course was held at dedicated simulator centers at Karolinska University Hospital in Stockholm or at Lund University Hospital. The curriculum of the course consisted of 6 hours of theoretical lectures in anatomy, pharmacology, complications, radiation safety and materials used in CA in combination with 6 hours of dyad non proficiency-based simulator training in CA. At all events we also had availability to a dummy to practice arterial and venous puncture (Seldinger technique).

To justify further use of simulators for CA training we wished to explore the transfer validity of the Mentice VIST™ in a randomized setting. In paper IV, twenty senior cardiology residents without CA simulator experience were recruited to participate. Four were not able to complete the study due to different circumstances. A stratified randomization was performed based on the outcomes of different tests at the start up meeting and the residents were matched two by two and then randomized to simulator training or control. The simulator group was instructed in how to handle the Mentice VIST™ and how to perform an accurate and safe CA. The teaching method used was the four step model for teaching practical skills (see above). The practice in the simulator was proficiency-based meaning that the participants had to reach the expert level in Mentice VIST™ (see paper II) before they could perform the procedure on patients. Expert proficiency level was set to; completing a CA within 10 minutes, 3 minutes of fluoroscopy time and less than 50 ml of contrast. There was no maximum level of simulator training time but the minimum level was estimated to be eight hours. When the participants could demonstrate expert level they continued with CA on patients. The control group was instructed to participate in 2 CA at their home hospital before continuing with CA in the study. At the catheterization lab both groups had received instructions on how to handle the table, C-arm, radiation protection and contrast injector. Two video-filmed consecutive CAs were then performed by all participants under supervision of an expert in CA blinded to their randomization. Data collection from the procedure regarding total procedure time, fluoroscopy time, amount of contrast, number of cine loops and radiation dose was performed. The 32 video recordings were assessed by a checklist regarding error and performance scores to assess the safety and quality of the procedures performed.

Cognitive training and assessment

In paper II, no theoretical course in CA was available and the instructions to the participants before the simulator evaluation were purely technical instructions in how to perform a CA and how to handle the simulator. However, the beginners group in paper II was familiar in theory how to perform a CA and of the coronary anatomy. Cognitive learning was achieved through cathedral lectures in CA and assessed with a summative written examination at the end of the course in study III. During the observation period of seven years in study III a web-course in CA was created by the author to facilitate and improve learning in CA and to prepare the participants before the start of the course. The web-course was available on-line at www.coronaryintervention.org and featured chapters for coronary anatomy, pharmacology, arterial puncture, complications, radiation safety and materials (Figure 5).

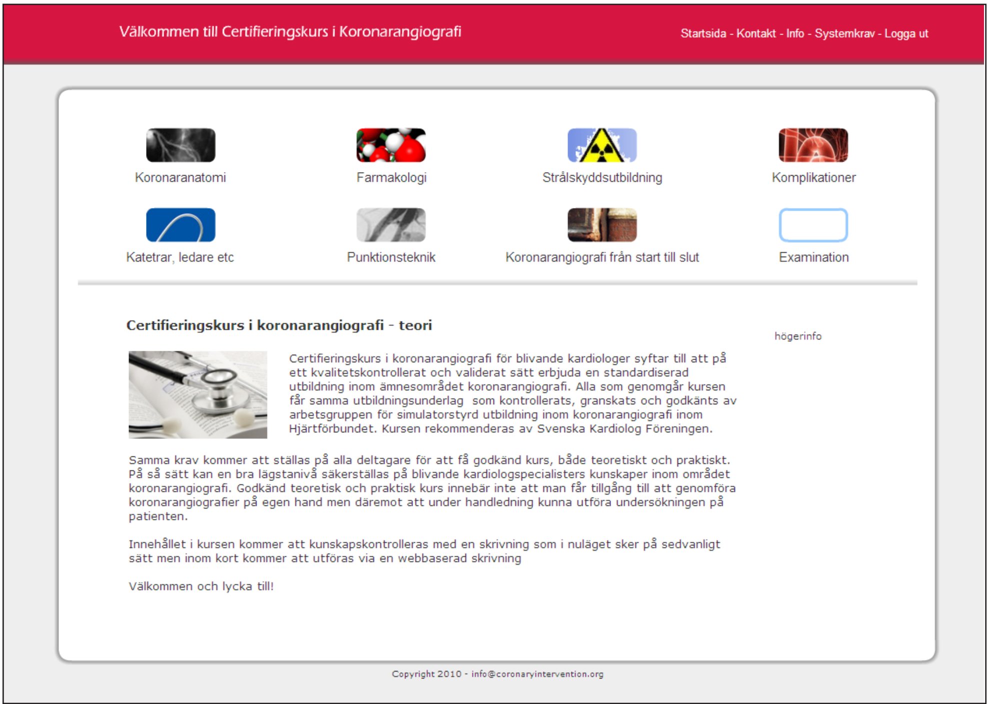


Figure 5. Screen print of the web-course in coronary angiography

Before the start-up meeting in study IV, the participants were instructed to study the web course in CA (see above) to equate their cognitive skills in CA. No other theoretical tutelage was provided. At the start-up meeting the participants completed a written examination based on the content from the web-course and performed a mental rotation test (MRT) to explore their visual-spatial abilities. They also filled in a survey regarding previous clinical experience and experience with simulators, invasive procedures and video games. Based on the results from the MRT and the written examination, simulator and catheterization experience, age and gender the participants were matched in pairs and thereafter randomized to simulator or control.

Simulator used

The Mentice VIST™ system, software 6.5 (Mentice, Gothenburg, Sweden) is a vascular intervention trainer including modules for intervention in femoral, iliac, aortic, renal, carotid, neural and coronary vessels (Figure 3). Incorporated is also one module for cardiac resynchronization therapy implantation. This simulator is a full scale simulator meaning that the entire procedure of CA, except introducer insertion, can be practiced. The interface includes a mannequin, two monitors and joysticks for table and C-arm control. The simulator is provided with buttons for zooming and x-ray intensity, and pedals for fluoroscopy and cine loop control. The machine accepts real interventional tools such as wires and catheters after the tip is cut off. The properties of the interventional tools, x-ray and cine loops are all simulated. Virtual contrast is created by injecting air by a syringe. Virtual haptics are produced by the simulator to get the sensation of tactile feedback. In this version of software a total of 31 anatomical coronary cases with different properties regarding anatomy of the aortic root and coronary lesions can be chosen from.

Statistics

Data are generally presented as median and inter quartile range (IQR) or mean ± SD or (range) and numbers (%). Descriptive summary statistics were used when appropriate. Mann-Whitney U-test was used when comparing two groups of data. Multiple regression analyses were used in study I to identify independent risk factors for complications. In paper II overall differences among multiple groups were tested with Kruskal-Wallis non-parametric test and with Mann-Whitney non-parametric test as a post-hoc test to compare differences between two groups. The level of significance of a test was specified at $p<0.05$. The significance level of the post-hoc test in study II was set to $p<0.01$ due to multiple testing. Analyses were performed using Statistica version 10, (Statsoft, Inc, Tulsa, OK, USA).

Ethical considerations

The protocols and procedures were approved by the local ethical committees for human research at Karolinska Institutet and at Uppsala University. The studies were performed according to the declaration of Helsinki and good clinical practice. Informed consent was provided by all participating residents, consultants and patients.

Results and Discussion

Paper I

In a retrospective case-control registry study, we investigated the performance curves of experts and beginners in CA based on potential proficiency parameters in the SCAAR registry. A total of 24 000 CAs were analyzed regarding performance metrics. Performance curves were constructed for the beginners group and demonstrated only in fluoroscopy time an actual improvement, thus a learning curve. These were compared to the expert's performances referred to as expert median performance and IQR. Fluoroscopy time was longer in beginners than in experts particularly when using the femoral approach. Beginners reached expert IQR in fluoroscopy time after about 140 CAs (Figure 6). Experts used femoral approach to a greater extent and investigated a higher proportion of previous coronary artery bypass grafting (CABG)-operated patients. Also the radial approach had the appearance of a learning curve in fluoroscopy time in beginners but was within the range of experts IQR. Experts used less contrast but the difference was minor and showed no sign of a learning curve (Figure 7).

The complication rate was all together low though more frequent in the beginners group and not demonstrating a learning curve. In a multiple regression analysis complications

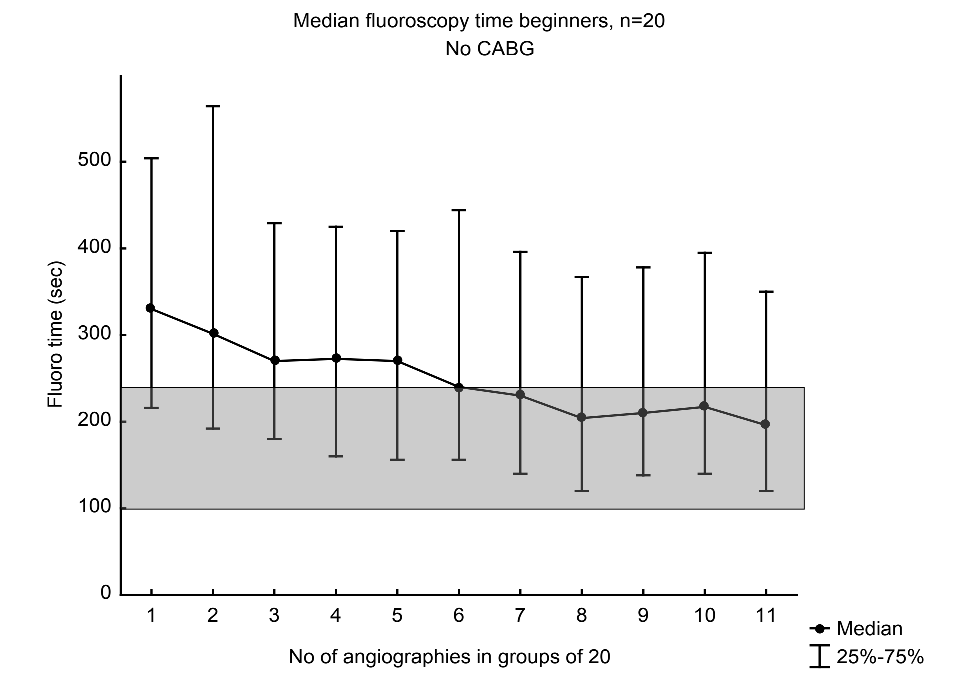


Figure 6. Median fluoroscopy time in beginners at all access sites in non CABG-operated patients. Grey area illustrating experts IQR.

seemed to be associated to fluoroscopy time and were independent of expertise, access site or previous CABG operation. The odds ratio for complication if fluoroscopy time exceeded 3 minutes was more than double.

Discussion

The results from this study support previous reports of performance curves in CA but adds new information about the type of learning curve that fluoroscopy time is associated with (82). Improvement in fluoroscopy time resembles the stop-start learning curve. We divided the performance into groups of 20 CAs to be able to see minor progression over time. However, the appearance and characteristics of this learning curve in CA is not in line with the two other studies exploring the same issue (82,83). The first study was a single center study assessing the performance of three advanced trainees. Only two intervals were used, the performance of CA 1-75 and performance of CA 76-150. In the second study they defined the proficiency level from a linear model approximated from trainee performances compared to experts from a single center. Only three performance intervals were analyzed, 1-100, 101-200 and 201-300. There is reason to believe that the learning curve in CA is not linear since we know that the fastest progress comes with the initial training when the trainee leaves the cognitive and enters the associative stage in the learning process. The progress here is usually relatively fast but slows down when the trainee becomes proficient and finally reaches the automated stage. Our conclusion that 150 CA should be considered to be a compulsory training volume before the learner performs CA unsupervised is in line with (ACC) (84) recommendations but not with the ESC training syllabus supporting 300 CAs to be performed by the general cardiologist (27).

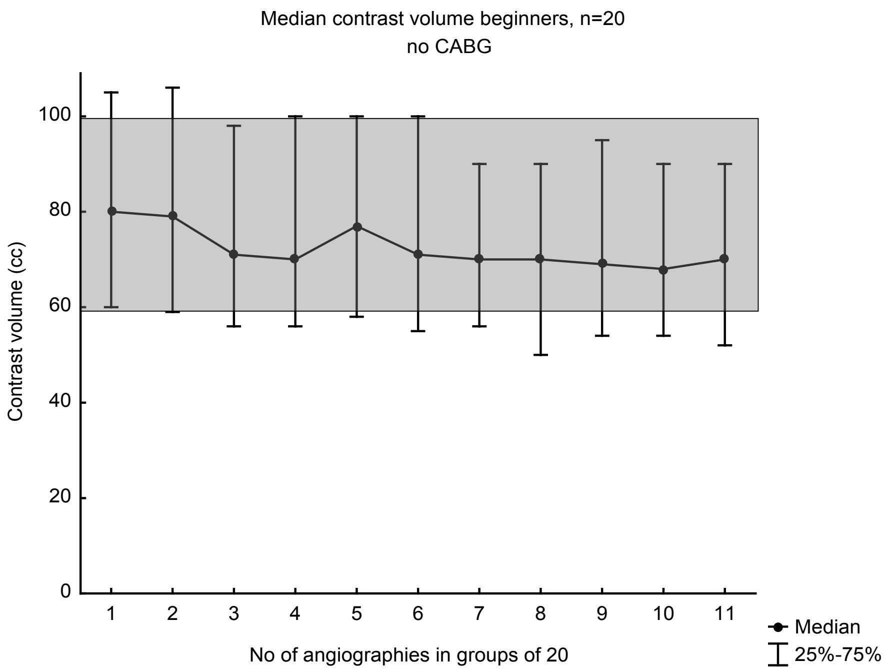


Figure 7. Contrast volume in beginners, all access sites in non CABG-operated patients. Grey area illustrating experts IQR.

Discussion about the advantages of different arterial access sites is highly up-to-date and controversies still exists about the advantages of the radial and femoral sites. We investigated separately both sites and could conclude that experts outperformed the beginners in fluoroscopy time, via the femoral approach, which in turn demonstrated a learning curve in the beginners group leveling out after about 150 CA. With the radial approach there was a similar learning curve in the beginners group reaching a steady state after about 150 CA but all the time within the experts IQR. When analyzing the expert's radial learning curve it had the appearance of the beginners. Conclusions drawn from this was that the experts started to use the radial approach during the observation period and hence most probably demonstrated a second learning curve. Most of the beginners started their CA career through the femoral approach but some had a mix of femoral and radial approaches and a few used predominantly the radial approach. What is right or wrong is still to be investigated. Also the number of complications was associated to the access site and the femoral approach demonstrated to be an independent predictor. Fluoroscopy time was associated to complications but whether this association is causal or not is hard to say. Fluoroscopy time increases if the patient is difficult to catheterize and is most often associated to anatomical circumstances. Extended catheter handling increases the risk for thrombo-embolic events and iatrogenic harm to the vessel wall (85). Prolonged fluoroscopy time is probably only a marker for difficulties in catheter handling and hence a surrogate marker for an increased risk for complications.

In summary

Fluoroscopy time can be used to construct learning curves in CA and proficiency is reached after performing about 150 procedures. A learning curve is demonstrated only in fluoroscopy time and is regardless of access site. Complications were few and demonstrated no learning curve. Our data suggests that fluoroscopy time is a surrogate marker for complications.

Paper II

To validate the Mentice VIST™ in CA, we aimed to investigate performance levels in three groups of cardiologists with different proficiency levels. The study was designed as a prospective non randomized case-control study of three separate groups of different performance levels with blinded assessment of performance skills.

Five video-recorded consecutive VR CAs were performed in one or two sessions by all participants. Experts outperformed trainees in all parameters measured by the simulator including the manually registered coronary intubation time. The intermediate group results were in between in all metrics. Beginners and experts performances were additionally assessed regarding quality measures using an error score checklist. Ninety percent of the experts VR CAs were without errors compared to 62% among the beginners who in turn had a four-fold increased risk of handling errors compared to experts (Figure 8).

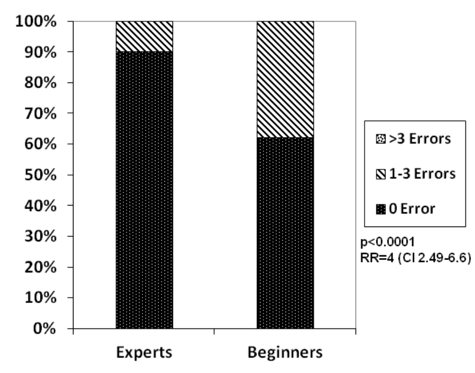


Figure 8. Handling errors in beginners and expert group based on catheter handling and respect for vessel during 100 VR CAs evaluated by two independent raters.

Comparing the three groups by non-parametric-testing of multiple independent groups revealed significant differences in all simulator metrics. Multiple testing two-by-two between the groups demonstrated a superiority of intermediates in total procedure time and contrast towards beginners. Likewise did the experts outperform the intermediates in total time, contrast and left coronary intubation time (Table 2).

Table 2. Results from Mentice VIST™ and manual assessed metrics

Metrics	Beginners	Intermediate	Experts	p-Value
Total time (sec)	1086 (879-1340)†*	817 (696-939)¤	622 (532-726)	<0.0001
Fluoroscopy (sec)	288 (227-416)*	228 (203-288)	212 (178-261)	0.0002
Cath-LCA (sec)	130 (90-185)*	98 (80-123)¤	80 (53-102)	0.0001
Cath-RCA (sec)	132 (80-210)*	96 (58-181)	76 (53-111)	0.0027
Contrast (ml)	173 (119-214)†*	108 (94-151)¤	46 (40-81)	<0.0001
Cineloop (#)	11 (10-12)†*	10 (10-11)	8 (8-10)	<0.0001

Data are presented as median (IQR). Cath= catheter, LCA=left coronary artery, RCA=right coronary artery. Statistical calculations are based on case 1-5. Kruskal-Wallis non-parametric test was used to explore differences between the groups. Mann-Whitney non-parametric test was used to test inter-group differences. p<0.01 marked (Beginners vs. Intermediate †), (Beginners vs. Experts *), (Intermediate vs. Experts ¤).

Discussion

Demonstrating construct validity is dependent on the accuracy and precision of the simulator to distinguish between different levels of proficiency, not just showing that there is a difference between experts and beginners. At least a third level is necessary to prove the concept of construct validity of the simulator and not just a gross tool to differentiate between poor and excellent. However, the number of available study subject can vary due to the estimated time spent in each proficiency level. Both beginners and experts are easy to find and only dependent on the definition. Intermediates are somewhat more crucial and more difficult to define. In this study, we managed to locate only four intermediates in CA by the definition of a cardiology resident with some experience in performing CA but less proficient than an expert. The reason for this is that soon after an operator has reached the necessary number for intermediate level they usually relatively soon progress to a higher level of performance and also start to do more advanced procedures, like PCI. For a beginner to be able to understand the procedure to be practiced in the simulator you have to have a cognitive base of knowledge. Medical students would not have been representative for a beginner because they are far from performing the procedure the forthcoming years. Cardiology residents have however reached the cognitive stage in the sense that they know the indications for the procedure and are aware of the coronary anatomy, something crucial for the understanding of the procedure. The metrics studied were all extractable from the simulator computer and they all managed to distinguish between the three groups. However, contrast use was three times higher in beginners than in experts, a fact that is not in line with the real world. In the SCAAR analysis (paper II) there was no learning curve in contrast use and a controversy regarding the sensitivity of this metric in the simulator has been discussed elsewhere (86). An interesting observation with the Mentice VIST™ is that the median fluoroscopy time detected among beginners and experts corresponds accurately to the reported mean fluoroscopy time in SCAAR (270 sec vs. 291 sec) in the beginners group and (168 sec vs. 188 sec) in the expert group, respectively (87).

Checklists were used to assess beginners and experts in the video-filmed VR CAs. Checklists were considered to be the option for assessing both groups despite the knowledge that global rating might be a better option for experts. However, the same method had to be used for both groups to be comparable. Two experienced cardiologists and CA operators had a high inter-rater reliability in error scoring of the video-filmed VR performances. Errors were identified as handling of catheters in a hazardous way or disrespect of the vessel wall, like introducing them in the wrong vessel or deep intubation into the coronary vessels. Beginners were inferior in procedure safety compared to the experts. The concept of construct validity for Mentice VIST™ has previously been shown in other endovascular procedures but this was the first successful attempt to prove construct validity for CA (83,86,88).

In summary

The Mentice VIST™ CA module can distinguish between different performances levels in simulator naive beginners, intermediates and experts. The differences were significant in all metrics extracted from the simulator. Experts outperformed the beginners in error score as a measure of procedure safety. The concept of construct validity of the Mentice VIST™ in CA was hereby confirmed.

Paper III

This study was designed as a retrospective case-control study with prospectively collected performance data from simulator training. The skills transfer effect from VR to real world catheterization lab was assessed in course participants advancing to CA operators as noticed in SCAAR regarding the same parameters used in study I. Fluoroscopy time was consistently longer among course participants than controls and showed less consistent improvement over time during the first 80 CAs (Figure 9).

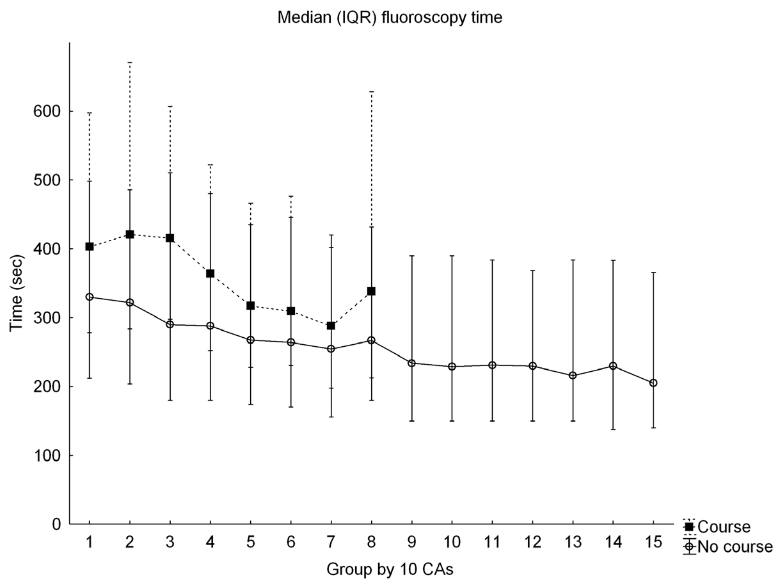


Figure 9. Median fluoroscopy time for course participants and controls representing the early learning curve. CAs = coronary angiographies.

Arterial access site or time from course to first solo CA did not influence the performance curves. When analyzing complication rates, they were more frequent in the course group, particularly when using the femoral approach (Table 3).

Table 3. Complications during the 80 first procedures.

Course	Lab comp	Ward comp	Fem lab comp	Rad lab comp	Fem ward comp	Rad ward comp
+ [12]	5/878 (0.57)	38/878 (4.33)	3/528 (0.57)	2/350 (0.57)	33/528 (6.25)	5/350 (1.43)
- [46]	33/3594 (0.92)	67/3594 (1.86)	19/1973 (0.96)	14/1620 (0.86)	50/1973 (2.53)	17/1620 (1.05)
Total	38	105*	22	16	83*	22

Numbers and (%). [participants]. * = p<0.001 tested by Chi-Square. Comp=complication, Fem=femoral, Rad=radial. + indicates course participants. – indicates controls.

Discussion

The attempt to demonstrate course validity of a structured simulator-based course in CA in this study failed. A majority of participants improved their performance skills in the simulator but did not manage to carry this knowledge to the real world procedure. It did not matter if the course event was interspersed between CAs in the participants that already had started to perform CA or if there was a long interruption between the course and their first CA, there was still no benefit for the course participants. The reason for that a structured simulator-based course in CA resulted in a worse performance is not clear. Supervision can be expected to be present during the initial CA in both groups but did the course participants behave differently during the real world CA procedure? A phenomenon known by virtual reality enthusiasts as “simulator behavior” might have played a role meaning that simulator trained trainees felt too comfortable in their situation and not concentrating enough or perhaps felt too self-confident and became arrogant in their attitude towards the difficulties in CA. Another possible reason is that the course curriculum was unsuitable. According to a survey completed after every course, it was highly appreciated and recommended by all participants reaching a scoring level of 5.6 of maximum 6. The simulator training was always supervised by experienced trainers and CA operators securing that no inappropriate behavior was automated. The training was also conducted in pairs, so called dyad training, known to increase the learning process so the conditions for successful practical training was optimal (89,90). Another possibility is that the simulator training was of insufficient quantity. The proficiency level in the simulator was not known at the time for these courses and might have changed the learning goals for the course curriculum and also the transfer effect. Previous failures to prove transfer validation of VR to real life have been reported in randomized settings and also in pooled analysis for several different procedures (91-95). One study showed an impaired performance after VR training but in a non-endovascular procedure (96). Course participants not only performed CA with worse results but also had more complications when using the femoral route. During the course a dummy was used to practice the Seldinger technique. The dummy was not validated and was not able to provide proximate feedback. Hence training without feedback might have resulted in an inappropriate learning and could be one explanation for the higher complication rate among the course participants. Selection bias of the course participants might be another explanation to the negative results. The course was officially announced in the whole country with voluntary attendance from all regions of Sweden. To say that the course was held for poor performers or operators that needed it the most is probably not accurate. During the observation period of seven years, 20 percent of all new operators in Sweden attended the course. Seven of the 12 participants had never performed a CA before the course event and they had no experience in catheterizations. The lack of knowledge in how they would perform a CA is hardly a motivation to their course attendance.

In summary

A structured simulator-based course in CA could not improve the early learning curve in CA in real life. The VR trained group improved their performance in the simulator but no effect was seen when performing CA on patients. The frequency of complications was higher than in the conventionally trained group. Transfer validation was not proved in this study. Randomized studies are warranted to justify VR training in CA to reduce the early learning curve.

Paper IV

Exploring skills transfer effect from VR CA to real world CA has not been evaluated before in a randomized setting. We designed a randomized controlled transfer study with blinded skills-, performance- and error assessment. Eight senior cardiology residents practiced in mean 10 hours up to expert proficiency level in the Mentice VIST™ CA module. The control group was not exposed to simulator training in CA but had identical pre-procedural instructions in the catheterization lab as the VR trained group (see Material and Methods). Two consecutive video-filmed CAs were performed by each participant. Proficiency metrics from the procedure demonstrated a superior performance by the simulator trained group in total time as well as fluoroscopy time (Figure 10). The conventionally trained group recorded in turn more cine loops.

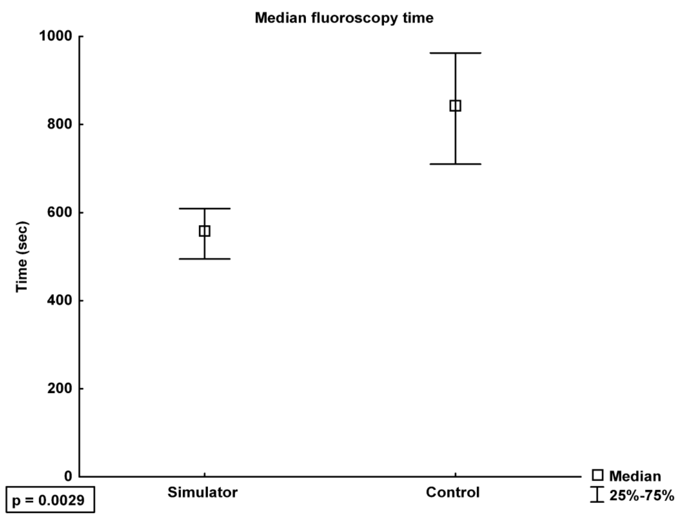


Figure 10. Result of median fluoroscopy time of 32 CAs performed by simulator and control group, respectively.

The simulator group outperformed the conventionally trained group in performance score and demonstrated fewer errors. Radiation dose and contrast used were comparable between the two groups (Table 4). Simulator trained residents with high MRT score had the highest estimated probability to reach the suggested proficiency and quality measures in real world CA.

Table 4. CA performance and assessment.

Variable	Simulator	Control	P-value
Total time (sec)	1356 (1171-1607)	1623 (1401-1890)	0.0317
Fluoroscopy time (sec)	558 (494-609)	842 (710-962)	0.0029
Contrast (ml)	88 (66-103)	100 (72-139)	0.3365
Radiation dose (DAP(Gy/cm^2))	46 (29-60)	55 (43-69)	0.3271
Cine loops (#)	9 (8-10)	10 (9-14)	0.0343
Error score	15 (11-20)	27 (22-32)	0.0017
Performance score: work flow	60 (48-65)	40 (35-50)	0.0088
Performance score: ability	14 (8-15)	7 (1-11)	0.0185
Performance score: total	68 (61-80)	47 (40-61)	0.0058

Values in median (IQR). Differences tested with Mann-Whitney U-test.

Discussion

Baseline characteristics between the groups were equal. The stratified randomization distributed potential confounders equally, in particular regarding MRT score, gender, age and results from summative cognitive testing (97,98). Proficiency based training in a CA simulator up to a pre-specified expert level in CA was superior to conventional master-apprentice training. Not only did the VR trained group perform better in metrics associated with time and number of cine loops but also in factors evaluated by a blinded assessor. Less errors and a general higher performance categorized the simulator trained residents thereby proving the concept of transfer validation. Fluoroscopy time has previously been described to be a surrogate marker for complications in CA and the superiority of the simulator group in this metric was pronounced. No complications occurred in any group but a longer series of CA might have revealed a benefit for VR training in that sense as well. Expertise in VR CA was reached after only 10 hours of unsupervised but formatively assessed practice. The VR performance skills level of experts were explored in paper II and served as training criterion for the simulator group. VR training was initiated after a short instruction of how to perform a CA and what to pay attention to in order to avoid dangerous behavior and the expert criterion training was reached without supervision. The reason for not having continuous supervised VR training was time. If simulators are going to be widely used in CA training there will unlikely be resources enough to have a supervisor at hand every time VR training is to be performed and most likely will the trainees practice when they have time in between in their daily practice. If resources were allocated for supervised VR training however, there might be an enhancement of the training effect. The role of MRT testing before training is an interesting concept. Since a high MRT score in combination with VR training created the best conditions for successful CA performance we might have a tool to find residents with the highest probability to succeed in invasive cardiology. Transfer validation in VR procedures regarding catheter-based procedures have only been demonstrated twice before. In 2006, Chaer et al. conducted a randomized study of 20 residents in general surgery performing two peripheral vascular interventions each. Their performances were assessed with global rating scores and demonstrated a higher score in the VR trained group (69). De Ponti et al. studied 2011, in a randomized setting training time and post-training performance in a total of 42 transseptal cardiac puncture after simulator training in 14 randomized cardiology fellows. Post-training time and performance score was higher in the VR trained group confirming transfer validity for that procedure. Power calculations of these trials were never described and perhaps difficult to conduct since the estimated benefit from VR training was hard to appreciate. In our study we could demonstrate an unmistakable benefit from simulator training in CA, however also without a power calculation. Perhaps based on these three transfer studies future randomized studies will be able to demonstrate an accurate estimation for power.

In summary

Proficiency-based simulator training in CA resulted in a superior performance in real life compared to conventional mentor-based training regarding quality and safety. Our recommendation is to incorporate simulator training into the curriculum for the general cardiologist.

General Discussion and Future Perspectives

Performing cardiovascular interventions without complications seems like a utopia but the general commitment must be an aim for zero tolerance for iatrogenic harm. In CA the number of complications is low but still a fact and they occur particularly during training. Would it be possible to reach a reality without any complications during CA? Probably not since unpredictable events will occur despite all precautions taken into consideration. However, we must at least do everything we can to optimize the conditions before, during and after the procedure to minimize harm. We would have to build a new training curriculum based on the state-of- art regarding training and assessment. With the basis from this thesis we could do a qualified attempt to outline this curriculum.

A validated curriculum in CA

The training has to be feasible and cost effective since time is a limitation in healthcare today. New working time directives binds all member states of the EU and will promote shorter working weeks as well as requirements for longer uninterrupted rest. Time for education and training will with high probability be reduced. Training must be efficient and aim for reduced number of complications. From what we know now, fluoroscopy time is a surrogate marker for complications in CA. The methods to reduce this could be through e-learning in order to exit the cognitive phase in CA as soon as possible and evaluate this with written examinations. When leaving the cognitive phase, simulator training has to be initiated in a well-validated CA simulator, in particular regarding transferability. Practice should aim for VR training up to proficiency level and until an autonomous stage is reached. At this level the learner is in the consciously competent stage and can then focus on patient safety and less concentration is needed to maneuver through the CA procedure. The motor skills needed to be practiced are fine muscle movements in an open environment, hence allowing the procedure to have unexpected challenges. The simulator should incorporate realistic unexpected complications or difficulties in the training cycles for the trainee to solve safely and properly. Fine acquired motor skills necessary for performing CA should be practiced in a serial approach and in progressive parts. Speed and accuracy in the movements should be promoted. When in expert proficiency state in the simulator it is time to move to the real procedure after a summative practical assessment using a checklist. In the catheterization lab the four step method for teaching practical skills should be used under close supervision. Skills practice must aim to improve speed and flow through the procedure because we know that fluoroscopy is a surrogate marker for complications. Distributed practice is recommendable and when the trainee is reaching a proficiency level in real life corresponding to 150 CAs an evaluation should be performed using a well designed global rating scale. Since the progress through the CA learning is highly individual it can instead be monitored through plotting a learning curve based on fluoroscopy time to be compared to the expert IQR based on the results from SCAAR. Recruiting proper candidates for advancement from general cardiology to invasive cardiology might be facilitated by using MRT scores since it seems to be associated to performance.

Complications and study power

The role of fluoroscopy time as a surrogate marker for complications could be an important issue and from what we know based on our studies; the goal for skills training in CA should aim for minimal time of fluoroscopy. According to paper I, the single most important factor for the likelihood for complications was a fluoroscopy time exceeding three minutes. This was independent of access site or if the patient had undergone previous CABG operation. The expert simulator training goal in study IV was a fluoroscopy time less than three minutes resulting in a superior performance in the simulator trained group both in safety and in performance. It is reasonably to think that an extended intravascular catheter time is related to an increased risk of thrombus formation inside the catheter, hence increasing the risk of embolization. Prolonged fluoroscopy time is also associated to difficulties in finding the coronary ostia and simulator training demonstrated to shorten both fluoroscopy time and coronary ostia intubation time in real life. It is therefore also reasonably to claim that simulator training in the long run will lead to fewer complications.

To date all randomized transfer validation studies demonstrating positive transfer effects were conducted with rather small trainee groups (see Table 1). The reasons for this are probably a limited access to appropriate trainees and a limited number of accessible simulators. Since the appreciated training effects in the different procedures are difficult to estimate, power in our studies were hard to calculate. In paper IV we could in 16 randomized residents show a distinct significant benefit from simulator training in the important procedure metrics and safety measures known to be associated to proficiency and therefore we must assume that power for the transfer study was obtained and sufficient.

Expert performance and talent

Even if the general opinion that quality training is more important than quantity one have to admit that Professor Ericsson´s theory that anyone practicing for 10 000 hours will be an expert in any skill is interesting (99,100). The problem is that few, if any, operators today considering themselves experts have spent 10 000 hours doing CA. Since a CA procedure takes approximately 30 minutes, it means that you have to have performed 20 000 CAs. In a busy practice you can perform 1000 CAs per year but you still have to work 20 years to become an expert according to Ericsson. Is it reasonably to think that if all CA operators would have practiced these hours, complications would never occur? Take an example from the individual sports world today. Tiger Woods is an expert golfer and considered to be an extreme talent as well. According to Ericsson theory of deliberate practice, talent does not exist and performance is strictly dependent on the amount of training. Tiger started to play golf when he was two years old appearing on a TV show, putting with Bob Hope. He has without doubt spent > 10 000 hours in the driving range and putting green practicing the same skill over and over again. The point is that athletes are able to practice without the circumstances surrounding a competition. For a CA operator training, with the exception for the simulator, does not exist. Every time CA is performed in the catheterization lab it is similar to a competition since there is always something at stake. However, patients can no longer be the practice arena. Every error has consequences, a fact that is the opposite to the practice arena. Virtual reality should be the safe alternative to real life practice since no life-threatening complications can occur. Getting automated in key skills in the CA procedure in a safe environment, just like Tiger on the driving range, before going real would probably be of great importance for error reduction i.e. reaching the autonomous stage according to Fitts and Posner (29). An idea would be to have a simulator at hand close to every catheterization lab and a compulsory warm up before every procedure and especially after longer periods of absence, like after vacations. If the concept of talent exist in performing CA it would probably be of minor importance since the virtual practice would not aim for quantity but instead of proficiency-based quality training with a well defined training curriculum.

Future aspects of simulator validation

Proving the concept of construct and transfer validities in CA for the Mentice VIST™ promotes the use of this simulator for skills acquisition. However, there are multiple training modules incorporated in this simulator but only three out of 12 procedures have been validated in a transfer setting; CA, transseptal puncture and peripheral vascular intervention (67,69). These results should not automatically be applied to the other modules and procedures but instead be validated in similar manner since all procedures are unique in their required skills and knowledge. Whether the transfer effect of CA in Mentice VIST™ is a general effect and applicable to other simulators providing CA training is unclear. Before we can prove a class effect we should promote more studies of proof of transfer validation from other simulators and procedures before incorporating them in training curricula.

Based on our results it does seem that Mentice VIST™ can transfer acquired skills in the simulator to the real world. In a follow-up study to study IV we will investigate the role of mental stress in training in the VR and in the real world performance by evaluation of heart rate, interviews and surveys regarding stress-related issues. Will preparatory VR training have a positive effect on the trainee´s comfort and stress level during real world procedures? And if that is the case could it be the true explanation of the positive transfer results from simulator training and not in achieving skills? Never assume the obvious is true!

Conclusions

I. Fluoroscopy time can be used to construct learning curves for coronary angiography (CA) training. Based on the results, our recommendation for trainees is to perform at least 150 CAs as primary operators before proceeding with unsupervised procedures. The complication frequency is low but significantly higher in beginners than in experts.

II. The Mentice VIST™ CA module can distinguish between simulator naive beginners, intermediates and experts in all metrics measured by the simulator computer indicating construct validity. Beginners performances did not reach the expert performances in a series of 5 CAs. Experts had fewer handling errors as a measure of procedure safety.

III. The use of simulators is not necessarily associated with improved learning. Cognitive and practical training with assessment by written examination and checklist without a well-defined training goal resulted in a less consistent learning curve and performance in catheterization lab. Simulator training in CA without proficiency-based expert goals is not recommended.

IV. Preparatory simulator-based training in CA is superior to conventional mentor-based training. Proficiency-based CA training in VR did result in a superior post-training performance measured by total procedure- and fluoroscopy time, and error- and performance scores thereby confirming transfer validity. Our recommendation is to incorporate proficiency-based VR training in the curriculum for the general cardiologist to improve safe learning of CA.

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